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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,995	09/26/2003	Richard G. Woodbury		3882

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1633

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,995

Applicant(s)

WOODBURY ET AL.

Examiner

Maria B. Marvich, PhD

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 2-25, 27, 28, 40 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 26, 29-39, 41-43 and 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The previous action mailed 7/28/06 is hereby withdrawn and replaced in its entirety with the following action, which was in response to a response to a restriction requirement filed 5/30/06. The previously mailed Forms 892 and 1449, however, will not be resent with this office action.

Election/Restrictions

Applicant's election of Group I (claim 1) in the reply filed on 5/30/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 1 has been amended. Claims 2-16, which originally depended from claim 1 have been cancelled and newly added claims 26-47 have been added to further limit claim 1. Based upon new claims 26-47, applicants have made a species selection of streptavidin as a domain molecule. Therefore, newly added claims 26, 29-39, 41-43 and 45-47 are drawn to the elected invention and claims 1, 26, 29-39, 41-43 and 45-47 are under examination in this office action.

Claims 2-25, 27, 28, 40 and 44 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/30/06.

Claim Objections

Claim 1 is objected to because of the following informalities: the claim recites that there are three domains but proceeds to recite “domain 1-GBP-domain 2” indicating that GBP is a domain. However, this would be more appropriately written as -- domain 1- GBP domain-domain 2-- .

Claims 1, 26, 29-39 and 45-47 are drawn to non-elected subject matter, which should be cancelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 26, 29-39, 41-43 and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of “reactive with at least one binding moiety or substrate” are unclear. The specification does not disclose domains that are “reactive with at least one binding moiety or substrate”. As such, it is unclear what is required of a domain to be “reactive” with binding moieties or substrates or what is exactly encompassed by a binding moiety or substrate such that it can “react” with a domain. As well, it is unclear that all of the recited domains in claim 26 have the capacity to be “reactive” with binding moieties or substrates.

Art Unit: 1633

Claims 29 and 31 are vague and indefinite in that the metes and bounds of “the GBP domain comprises one or more (1 to 7) repeated amino acid sequences as set forth in SEQ ID NO: 17”. As recited the claim indicates that the GBP domain comprises one or more repeated sequences that are within SEQ ID NO:17 whereas it appears applicants intend that the GBP domain in its entirety is repeated. It would be remedial to amend claim 29 and 31 to recite that the GBP domain comprises – one or more copies—(claim 29) -- one to seven copies of – (claim 31) the amino acid sequence of SEQ ID NO: 17.

Claim 34 is vague and indefinite in that the metes and bounds of “low complexity” are unclear. The term “low” is a relative one not defined by the claim, no single set of conditions is recognized by the art as being “low” and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established.

Claim 47 is vague and indefinite in that the metes and bounds of “the vector comprises a host cell” are unclear. It is unclear how a nucleic acid vector can comprise a host cell.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 26, 29-39 and 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled

Art Unit: 1633

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation that GBP is linked to domain 1 and domain 2 that “are reactive with at least one binding moiety or substrate” has been added to claim 1. As well, applicants recite that this domain can be core streptavidin, avidin related protein 4/5, strep-tag, strep-tagII, antibody, antibody fragment, and biotin in newly added claim 26. Applicant has not indicated where support for this limitation is found. The examiner has been unable to find support in the originally filed specification for the term “reactive with at least one binding moiety or substrate” or that the “fusion” domain is core streptavidin, avidin related protein 4/5, strep-tag, strep-tagII, antibody, antibody fragment, and biotin. Rather, the specification teaches that GBP is fused to a fusion partner and this partner can be a number of fusion partners. The fusion partner can be protein A, protein G, streptavidin, SCA, enzymes, receptors, peptides suitable for introduction of biotin, affinity binding peptides, peptides with selective binding affinity to specific proteins or other macromolecules or organic molecules. However, the specification does not teach that this fusion partner is limited to domains that are “reactive” with at least one binding moiety or substrate. As well, the specification teaches that the fusion partner can be streptavidin or avidin or related molecules but do not disclose any of the specifically recited ones such as core streptavidin, neutravidin, etc. The specification discloses use of single chain antibody but not antibodies or antibody fragments. The specification discloses use of peptides that bind biotin but not use of biotin. As well, the limitation that linkers between the domains are of “low complexity” has been added by addition of newly added claim 34. Applicant has not indicated

Art Unit: 1633

where support for this limitation is found. The examiner has been unable to find support in the originally filed specification for the term "low complexity".

Therefore, the added limitations are impermissible NEW MATTER.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 26, 29, 32, 37 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botti et al (2006/0128944; see entire document) in view of Brown et al (Nature Biotechnology, 1997, Vol 15, Pages 269-272; see entire document).

Applicants claim a nucleic acid comprising domain 1- GBP-domain 2.

Botti et al teach a nucleic acid encoding a streptavidin tag- a metal binding domain- a His6 tag. Both domain 1 and 2 are "reactive" with either a binding moiety- His binding moiety for His6tag and biotin for streptavidin given that reactive is interpreted as meaning that the two components interact. The MBP is separated from strep with a linker while His6 is typically fused to molecules by aid of a linker (see e.g. figure 7 and ¶0061). The constructs are expressed on vectors and used to transform cells (¶0376 and ¶0397).

Botti et al do not teach that the metal binding domain if GBP with sequence of SEQ ID NO:17.

Art Unit: 1633

Brown et al teach that a 7 repeat motif of a GBP with a sequence of SEQ ID NO:17 can be coupled with specific recognition elements that can serve as a purification tool (table 1).

Brown teaches that the repeating polypeptides are amenable to structural analysis in spite of their size. As well, hybrid proteins containing the peptide can be easily immobilized on metallic surfaces (page 271, col 1, ¶ 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the metal binding domain as taught by Botti et al with the Gold binding peptides taught by Brown et al because Botti et al teach fusion of a metal binding domain with streptavidin and his tags and because Brown et al teach that it is within the ordinary skill of the art to generate a fusion construct with gold binding peptides and recognition elements such as purification elements. One would have been motivated to do so in order to receive the expected benefit of amenable structures that can be used to easily immobilize proteins on gold surfaces. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

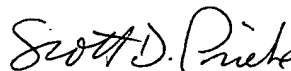
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

Art Unit: 1633

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER